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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,492	11/20/2001	Yasuhiro Sando	15162/04190	8558

24367 7590 12/18/2003

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EXAMINER

SINES, BRIAN J

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 12/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/988,492

Applicant(s)

SANDO ET AL.

Examiner

Brian J. Sines

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 20-25 is/are rejected.
- 7) ☒ Claim(s) 19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

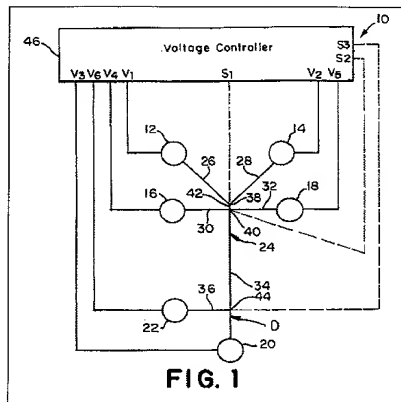
***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4 – 9, 12 – 15, 17, 18, 20, 21, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Ramsey (U.S. Pat. No. 5,858,195 A). Regarding claims 1, 4, 7 – 9, 12, 13 and 21, Ramsey teaches an apparatus comprising: a first channel or specimen flow pass (*e.g.*, 26); a second channel or reagent flow pass (*e.g.*, 28) in fluid communication with the specimen flow pass; a confluence flow pass (38, 40 & 44); a sensing portion; and a force applying means (*e.g.*, electrokinetic fluid transport *via* voltage controller 46) (see col. 6, line 60 – col. 8, line 20; figures 1 & 30). Ramsey teaches that with laser-induced fluorescence, the point of detection can be placed anywhere along the separation column (see col. 21, lines 33 – 46). Ramsey teaches that the substrate or base of the microchip can be fabricated from a clear material, such as glass, which would be an effective window, and thereby facilitate sample detection using optical methods (see col. 8, lines 21 – 36). Ramsey teaches that the apparatus comprises a plurality of microchannel branches (26, 28, 30, 32, 34, 36 and 38) (see col. 6, lines 60 – 67; figure 1).



Regarding claims 5 – 7, 14, 15 and 21, these claims recite various process or use limitations, which do not further delineate the structure of the claimed apparatus from that of the prior art. Since these claims are drawn to an apparatus statutory class of invention, it is the structural limitations of the apparatus, as recited in the claims, which are considered in determining the patentability of the apparatus itself. These recited process or use limitations are accorded no patentable weight to an apparatus. For example, these claims recite how the apparatus is to be operated or what is intended to be used or detected using the apparatus, such as microparticles, which do not impart any limitations to define the structure of the apparatus being claimed. Process limitations do not add patentability to a structure, which is not distinguished from the prior art. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967); and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The Courts have held that it is

well settled that the recitation of a new intended use, for an old product, does not make a claim to that old product patentable. See *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987) (see MPEP § 2114).

Regarding claims 17, 18 and 20, as discussed above, Ramsey teaches all of the structure provided in the claimed detection method, which merely recites the conventional operation of that structure. Regarding process or method claims, a prior art device anticipates a claimed process, if the device carries out the process during normal operation (see MPEP § 2112.02). The Courts have held that when a prior art device is the same as a device described in the specification for carrying out the claimed method, it can be assumed that the device will inherently perform the claimed process. See *In re King*, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986). Ramsey teaches that reaction chamber (24) can be used to mix any two chemicals, such as a specimen sample (*e.g.*, DNA) and an added microparticle (*e.g.*, enzymes, fluorescent labels, *etc.*). Ramsey teaches that an appropriate detector (D) could then be employed to analyze the labeled materials between the third intersection (44) and the fifth reservoir (20) (see col. 7, line 64 – col. 8, line 20).

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 3, 10, 11, 16, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramsey in view of Bentsen *et al.* (U.S. Pat. No. 6,375,871 B1). Ramsey does not specifically teach the incorporation of a micropump. Ramsey does teach the use of electrokinetic transport as a pumping mechanism in microfluidic devices (see col. 7, lines 28 – 32). Bentsen *et al.* do teach microfluidic devices having microchannels having vertically tapered inlet and outlet diffusers for piezoelectric valve-less diffuser micropumps for facilitating fluid transport (see col. 4, lines 36 – 48). Both of the pumping mechanisms are well known in the prior art for being utilized for the same intended purpose, for facilitating fluid transport within microfluidic devices, as evidenced by Bentsen *et al.* and Ramsey. Hence, these pumping mechanisms are considered functional equivalents clearly recognized in the prior art (see MPEP § 2144.06). The Courts have held that an express suggestion to substitute one equivalent component or process for another is not necessary to render such a substitution obvious. See *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the known equivalent pumping mechanism, as

taught by Bentsen *et al.*, with the microfluidic apparatus of Ramsey in order to facilitate effective fluid transport.

Furthermore, these claims recite various functional limitations, such as the flow pass impedance characteristics of the micropump. In a claim drawn to an apparatus statutory class of invention, a functional limitation may not be divorced from any specifically recited structure or composition. A functional limitation is an attempt to define an apparatus by what it does, rather than by what it is, *as evidenced by its specific structure* (emphasis added) (see MPEP § 2173.05(g)). Regarding product and apparatus claims, when the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent (see MPEP § 2112.01). The Courts have held that where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. See *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). The Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, *not function* (emphasis added). See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP § 2114).

***Allowable Subject Matter***

Claim 19 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:  
The cited prior art neither teach or fairly suggest the further incorporation within the method of detection the fourth step of measuring a time period until the reciprocal movement of the microparticles stop.

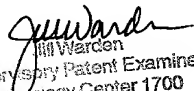
***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wurzel *et al.* teach a microfluidic analytical system. Anderson *et al.* teach a miniaturized integrated nucleic acid diagnostic device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (703) 305-0401. The examiner can normally be reached on Monday - Friday (11:30 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700